

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Quality Improvement Organization (QIO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier;

(v) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(vi) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

APPENDIX A TO SUBPART C OF PART 1001

The following is a sample written disclosure for purposes of satisfying the requirements of §1001.952(v)(3)(i)(B)(I)(i) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

NOTICE OF AMBULANCE RESTOCKING PROGRAM

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert de-

scription of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in §1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated: _____

/s/ _____

Appropriate officer or official

[66 FR 62991, Dec. 4, 2001]

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State

health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid and other Federal health care programs in ac-

cordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) CMS will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.